K111341 1 of 3

510(k) Summary

SEP 26 2012

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products, Division of Ethicon, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person
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Manager, Regulatory Affairs
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Summary Date: September 10, 2012

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Biological Sterilization Process Indicator
Common/Usual Name:	Biological Indicator (Test Pack)
Product Classification:	II
Classification Regulation:	21 CFR 880.2800
Proprietary Name:	STERRAD® 100NX® DUO Cycle Test Pack

2. PREDICATE DEVICES

STERRAD® 100NX® Test Pack, K071537 cleared on December 18, 2007

3. INDICATIONS FOR USE

The STERRAD® 100NX® DUO Cycle Test Pack is used for routine monitoring of the STERRAD® 100NX® DUO Sterilization Cycle and is also used for the periodic testing of a STERRAD® 100NX® System DUO Cycle, using hospital-defined loads containing devices that do not exceed claims of the cycle. The STERRAD® 100NX® DUO Cycle Test Pack consists of a STERRAD® CYCLESURE® 24 Biological Indicator, vial and cap to hold the BI.

4. DESCRIPTION OF DEVICE

The STERRAD® 100NX® DUO Test Pack consists of a CYCLESURE® 24 Biological Indicator (BI) and a STERRAD® NX® Test Vial with cap for holding the BI during the sterilization cycle.

5. SUMMARY OF NONCLINICAL TESTS

The STERRAD® 100NX® DUO Test Pack has been evaluated for its resistance to the DUO Cycle in the STERRAD® 100NX® Sterilizer.

A comparison of the DUO Test Pack to the biological model developed for the DUO Cycle indicates that the Test Pack is at least as resistant to the sterilization process as the biological model. This is based on both survival curves and fraction negative data as a function of dose.

DUO Test Packs assembled from three lots of CYCLESURE® 24 Biological Indicator (BI) were exposed to several doses of hydrogen peroxide in a DUO Cycle. These survivor curves were compared to the survivor curves for the biological model developed for the DUO Cycle. The test data showed that the Test Pack configuration was at least as resistant as the biological model.

Additionally, fraction negative data were collected using Test Packs assembled from three lots of CYCLESURE® 24 BI and exposed to increasing volumes of hydrogen peroxide in a DUO Cycle. The results indicated that the Test Pack configuration was at least as resistant as the biological model.

Indicative functionality of the chemical indicator in a DUO Test Pack configuration was evaluated using half-cycle parameters of the DUO Cycle and the response was determined to be appropriate for a chemical indicator.

The subject device and its predicate device have the same intended use which is for routine monitoring of the sterilizer cycle. Additionally, they have the same technological characteristics, the same operating principles and are subjected to the same sterilant (hydrogen peroxide) and therefore, the subject device is substantially equivalent to the predicate.

The Table below lists the tests performed to demonstrate that the DUO Test Pack functions as intended in the STERRAD® 100NX® sterilizer using a DUO Cycle.

Studies Performed	Results
Design Evaluation and Performance Qualification of STERRAD® 100 NX® DUO Test Pack	Passed
Functionality Study of the Chemical Indicator Disc of CYCLESURE® 24 BI in Test Pack	Passed

6. DESCRIPTION OF CHANGE:

- Indications for Use Statement has been revised to incorporate the STERRAD® 100NX® DUO Test Pack.
- Instructions for Use have been revised to include STERRAD® 100NX® DUO Test Pack information.

7. OVERALL PERFORMANCE CONCLUSIONS

The performance data shows that the STERRAD® 100NX® DUO Test Pack has the necessary resistance relative to the biological model to be an appropriate challenge for testing the DUO Cycle of the STERRAD® 100NX® Sterilizer and it is substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Nancy Chu
Manager, Regulatory Affairs
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

SEP 26 2012

Re: K111391
Trade/Device Name: STERRAD® 100NX® DUO Cycle Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: September 10, 2012
Received: September 12, 2012

Dear Ms. Chu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111391

Device Name: STERRAD® 100NX® DUO Cycle Test Pack

Indication for Use:

The STERRAD® 100NX® DUO Cycle Test Pack is used for routine monitoring of the STERRAD® 100NX® DUO Sterilization Cycle and is also used for the periodic testing of a STERRAD® 100NX® System DUO Cycle, using hospital-defined loads containing devices that do not exceed claims of the cycle. The STERRAD® 100NX® DUO Cycle Test Pack consists of a STERRAD® CYCLESURE® 24 Biological Indicator, vial and cap to hold the BI.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __√__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ECA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111391